

Amendments to the Claims:

This listing of claims will replace all prior versions and listing of claims in the application.

Please cancel claims 1 to 97 without prejudice or disclaimer

Please add new claims 98 to 135.

1 to 97. (canceled)

98. (new) A method for inactivating at least one biological contaminant or pathogen in a preparation containing albumin comprising irradiating said preparation with gamma radiation at a rate of greater than 3.0 kGy/hr for a time effective to inactivate at least one biological contaminant or pathogen in said preparation.

99. (new) A method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation comprising irradiating said preparation with gamma radiation at a rate greater than 3.0 kGy/hr for a time effective to inactivate at least one biological contaminant or pathogen in said preparation.

100. (presently amended) A method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation comprising reducing the temperature of said preparation to a level effective to protect said preparation from gamma irradiation; and irradiating said preparation with gamma irradiation for a time effective to inactivate at least one biological contaminant or pathogen in said preparation.

101. (new) The method according to claim 98, 99 or 100 further comprising reducing residual solvent present in said preparation to a level effective to protect said preparation from said gamma radiation.

102. (new) The method according to claim 98, 99 or 100 further comprising adding to said preparation at least one stabilizer in an amount effective to protect said preparation from said gamma radiation.

103. (new) The method according to claim 98 or 99, further comprising reducing the temperature of said preparation to a level effective to protect said preparation from said gamma radiation.

104. (new) The method according to claim 98 or 99, further comprising at least two of
(i) reducing residual solvent present in said preparation to a level effective to protect said preparation from said gamma radiation;

(ii) adding to said preparation at least one stabilizer in an amount effective to protect said preparation from said gamma radiation; and

(iii) reducing the temperature of said preparation to a level effective to protect said preparation from said gamma radiation.

105. (new) The method according to claim 99 or 100 wherein said plasma protein fraction comprises albumin.

106. (new) The method according to claim 99 or 100 wherein said plasma protein fraction further comprises at least one protein selected from the group consisting of a coagulation protein, a lipoprotein and a complement protein.

107. (new) The method according to claim 104, wherein said coagulation protein is at least one selected from the group consisting of Factor VII, Factor VIII Factor IX and von Willebrands factor.

108. (new) The method according to claim 99 or 100 wherein said plasma protein fraction further comprises at least one biological material selected from the group consisting of hemoglobin, alpha-globulin, beta-globulin and gamma-globulin.

109. (new) The method according to claim 98 or 99 wherein said rate is greater than about 6.0 kGy/hr.

110. (new) The method according to claim 98 or 99 wherein said rate is greater than about 18 kGy/hr.

111. (new) The method according to claim 98 or 99 wherein said rate is greater than about 30.0 kG/hr.

112. (new) The method according to claim 101 wherein said residual solvent is water.

113. (new) The method according to claim 101 wherein said residual solvent is an organic solvent.

114. (new) The method according to claim 101 wherein said residual solvent is reduced by a method selected from the group consisting of lyophilization, concentration, addition of solute, chemical extraction, spray-drying and vitrification.

115. (new) The method according to claim 101 wherein the content of said residual solvent present in said preparation after said reduction is less than about 10%.

116. (new) The method according to claim 101 wherein the content of said residual solvent present in said preparation after said reduction is less than about 5%.

117. (new) The method according to claim 102 wherein said at least one stabilizer is an antioxidant.

118. (new) The method according to claim 102 wherein said at least one stabilizer is a free radical scavenger.

119. (new) The method according to claim 102 wherein said at least one stabilizer is selected from the group consisting of ascorbic acid or a salt or an ester thereof; DMSO, mannitol, trehalose, glutathione; 6-hydroxy-2,5,7,8-tetramethylchrom-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate and gallic acid or a salt or an ester thereof.

120. (new) The method according to claim 100 wherein said temperature is reduced below ambient temperature.

121. (new) The method according to claim 100 wherein said temperature is reduced below the freezing point of said preparation.

122. (new): The method according to claim 100 wherein said temperature is reduced below the eutectic point of said preparation.

123. (new) The method according to claim 100 wherein said temperature is reduced below 0°C.

124. (new) The method according to claim 100 wherein said temperature is reduced below minus 40°C.

125. (new) The method according to claim 100 wherein said temperature is reduced below minus 60°C.

126. (new) The method according to claim 98, 99 or 100 wherein said gamma irradiation is administered for a time effective to sterilize said preparation.

127. (new) The method according to claim 98 wherein the preparation containing albumin is selected from the group consisting of Albuminar®, Buminate®, Albutein® and Albumarc®.

128. (new) The method according to claim 99 or 100 wherein the plasma protein fraction preparation is selected from the group consisting of Plasma-Plex®, Protenate® and Plasmatein®.

129. (new) The method according to claim 99 or 100 wherein the plasma protein fraction preparation is Plasmanate®.

130. (new) A biological composition produced by any of the methods of claim 98, 99 or 100.

131. (new) The composition of claim 130 wherein the composition is sterile albumin.

132. (new) The composition of claim 130 wherein the composition is sterile plasma protein fraction.

133. (new) A method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation comprising irradiating said preparation with gamma radiation for a time effective to sterilize said preparation.

134. (new) A method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation consisting essentially of irradiating said preparation with gamma radiation for a time effective to sterilize said preparation.

135. (new) A method for inactivating at least one biological contaminant or pathogen in a plasma protein fraction preparation consisting of irradiating said preparation with gamma radiation for a time effective to sterilize said preparation.